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The Valley Hospital of Ridgewood, New Jersey, is proposing to extend a limited but highly successful specimen management and medication administration medical errors reduction initiative on a hospital-wide basis. The program designed to reduce specimen collection errors at The Valley Hospital is rooted in utilization of bar-code technology in tandem with the use of handheld personal data terminals to create a positive identification system at the point of care. The system is currently implemented in five patient care units and working with great success to minimize error.

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INTRODUCTION

The program designed to reduce specimen collection errors at The Valley Hospital is rooted in utilization of bar-code technology in tandem with the use of handheld personal data terminals to create a positive identification system at the point of care. The system is currently implemented in five patient care units and working with great success to minimize error.

This work proposes to expand the existing specimen collection model to eighteen patient care units. It will then study the question of whether a system for the reduction of specimen errors can maintain its performance rate when instituted for collection of all specimens in the hospital. The ability to do this work will be dependent on the Human Subjects Protection Review Boards approval of the Human Use Protocol.

BODY

The first year's work on the protocol Medical Errors Reduction Initiative, follows two tracks. One is the technical development and the other is getting research protocol approval through the Human Subjects Research Review Board (HSRRB). Significant work has been accomplished on each track however they remain a work in progress.

To date, expansion of the point of care specimen collection system using handheld devices beyond the five patient care units has not been able to occur. Expansion of the project and conduct of the research is predicated on the approval of the human use protocol by the HSRRB. The following is the outline of the course of events as it applies to the human use protocol:

- June, 2004 Melanie Oringer of the Human Subjects Protection office called to indicate that a human use protocol needed to be written. The protocol was written and submitted to the Human Subjects Office (HSO) on 16 August 2004.

- On 05 November 2004, a Memorandun for Record was sent by Melanie Oringer, Human Subjects Protection Scientist at the HSO.

- On 23 November 2004, the request for changes were made to the human use protocol as outlined in the memo and was hand delivered to the HSO.

- On 15 February 2005 a second Memorandum for Record was sent by the HSO. At this time, the Principal Investigator's response to the second Memorandum for Record is being prepared for submission to Melanie Oringer by mid-May 2005.

The writing of the protocol and the revisions requested has consumed a great deal of preparation time during the first year of this award. Depending on the date of approval of the human use protocol, the Statement of Work will need to be modified on some of the target completion dates. (Attachment 1)

While work on the human use protocol was taking place, the technical developments were being worked on. A bi-directional interface needed to be written to maximize the error reduction with the specimen collection technology. The specification was written and agreed upon between the two vendors and the client. The interface was written, installed and tested.

The interface testing utilized live real-time data to determine the accuracy of transfer, as well as the timeliness of the data transfer. This procedure tested the volume of data passing through the interface at a given time. This is an important element, particularly in the Emergency Department when availability of a specimen order for processing and receipt to the lab will be critical to result turn around.

The system vendor advised that the stability of the bi-directional interface is the most critical element in the successful operation of the system. Based on the information the conversion to pocket personal computers in the first five units will be postponed to the third quarter of 2005.

A test patient database has been developed to test the accuracy of information flow between the handheld used at the bedside as well as the information flow from the laboratory information system. Lastly, the patient status and location were important to the system to send the orders for processing by the laboratory. The development of the training database, the test scenarios and the training program has been completed.

The vendor in tandem with the clinic education staff developed a training database mimicking each specimen type and scenario. The goal was to make it all inclusive, intuitive and efficient. The training database addresses the steps in the process, the safety features of the software and hardware to the specimen collection process. It accomplishes this for each type of specimen to be collected. Included is the labeling of the sample and the transport of the specimen to the lab.

The training has been time tested to be accomplished within two hours. The clinical education department took into account different adult learning styles as well as flexible work schedules when developing the training program. A mobile training cart has been set up so it can be moved to various locations to meet the needs of the staff. This has been done with a laptop computer, a set of handheld personal data terminals and printers connected to the hospital's local area network.

The training database is complete, the user scenarios are integrated and the program has been time tested. A training manual has been written for the trainers use in the class as well as a take-away for future reference. The educators have coordinated space and have designed a process to make this a mobile training setup. They will be able to train in the classroom as well as on the nursing unit.

A workflow assessment has been done in the Emergency Department to determine placement of hardware as well as the appropriate amount of equipment to maximize ease of accessibility for the staff.

Currently, research staff are completing the National Institute's of Health, Human Participant Protections Education for Research Teams program then they will become certified. Once final approval of the research protocol by the HSRRB is granted, the research can begin.

KEY RESEARCH ACCOMPLISHMENTS

Technical Components

- Bi-directional Interface written and tested
- Hardware assessment and placement

Training Program

- Development of software with user training scenarios
- Writing of training manual
- Time tested training program
- Develop a mobilized training program

Human Use Protocol

- Protocol has been written
- Submitted with two revisions
- Presently awaiting final approval

APPENDIX I

Statement of Work

The program designed to reduce specimen collection errors at The Valley Hospital is rooted in utilization of bar-code technology in tandem with the use of handheld personal data terminals to create a positive identification system at the point of care. The system is currently implemented in five patient care units and working with great success to minimize error.

This work proposes to expand the existing specimen collection model to eighteen patient care units. It will then study the question of whether a system for the reduction of specimen errors can maintain its performance rate when instituted for collection of all specimens in the hospital. The ability to do this work will be dependent on the Human Subjects Protection Review Boards approval of the Human Use Protocol.

Once the Protocol has been approved, work is proposed to begin in the second half of 2005 of this two year project. The protocol identifies the study to take place in the Emergency Department and then expand to eleven additional patient care units. Variability between human monitoring studies done prior to the system implementation and errors rates post implementation will be compared. The latent error rate reported using the specimen collection system over time will be measured against worker turnover to determine any potential variance. Quarterly reports will be provided to the Department of Defense (DOD) according to their specifications.

The second year will entail three components of work. First, the balance of six additional patient care units implement the system following the outline above. The second phase will be the conversion of five units to the use of pocket personal computers from personal data terminals. The third phase will be the addition of other point of care processes namely, medication administration and blood transfusion. Comparison of the expressed error rate using locale-optimized specimen collection versus a general specimen collection management system will be compiled.

The conversion of the hardware to pocket personal computers will then begin on each of the five units sometime in the third quarter 2005. Impact of the use of the new hardware on expressed and latent error rates will be measured and quarterly reports will be provided.

Beginning the third quarter of 2005 through the end of the year, software will be installed and dictionaries will be built. In the first quarter of 2006, staff will be trained, one unit at a time, in the process of point of care medication administration. This clinical application will integrate specimen collection result information as it relates to specific medications. Evaluation of user impact on expressed and latent errors will be conducted. Quarterly reports will be provided.

In the last quarter of 2005 the implementation of a point of care transfusion module will be added to one patient care unit assess the latent error rate for transfusion utilizing a third point of care application on a hand-held. A complete and in depth evaluation will be delivered to the DOD upon completion of this cooperative agreement.